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Virginia Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Patients Faxing Their Prescriptions

Occasionally, the Virginia Board of Pharmacy is contacted by either pharmacists or patients who are inquiring whether a patient may fax a prescription directly from home to the pharmacy and then present the original prescription to the pharmacist at the time of picking up the dispensed drug. The desire, of course, is to prevent the patient from having to wait while a prescription is being dispensed. This, however, is not allowed for multiple reasons.

First, a faxed prescription, as stated in Board Regulation 18VAC110-20-280, shall be valid only if faxed from the prescriber's practice location, except for forwarding a faxed chart order from a long-term care facility or from a hospice. Therefore, a pharmacist may not fill a prescription pursuant to an improperly faxed prescription, regardless of whether the original prescription is reviewed prior to releasing the drug. Secondly, problems may result from having to rely upon a patient to remember to bring the pharmacist the original prescription, or trusting that another staff pharmacist will remember to obtain the original prior to releasing the drug. Therefore, the Board has never allowed this practice.

In summary, pharmacists should not advise patients to directly fax the pharmacy their prescriptions, and may not prepare a drug for dispensing pursuant to a prescription that has not been properly faxed from the prescriber's practice location. The pertinent regulation regarding transmission of a prescription order by facsimile machine may be accessed at *www.dhp.virginia.gov/Pharmacy/leg/Pharmacy_11292006.doc#_Toc153072935*.

Dispensing with the Correct Prescriber's Name

With the exception of drugs dispensed in a hospital pursuant to a chart order, a pharmacist is required by §54.1-3410 to include on the prescription label the name of the prescriber who wrote the prescription. Frequently, the Board receives complaints from physicians who state that a prescription was dispensed with their name appearing on the label as the prescriber, but the physicians show no record of ever seeing the patient or prescribing the drug. This problem seems to occur often when the prescription was prescribed by a nurse practitioner and perhaps the pharmacy does not have record of the nurse practitioner's Drug Enforcement Administration (DEA) number. The pharmacist then appears to simply assign the prescription to another physician in the practice for whom the pharmacist has the DEA number on file. This is considered mislabeling and as such is a violation of law.

As a reminder, nurse practitioners with prescriptive authority and physician assistants may prescribe drugs in Schedules II through VI. Additionally, they must have a DEA number if they wish to prescribe Schedules II through V. This DEA number should be included on the prescription written for any drug in Schedules II through V.

To review the aforementioned statue, §54.1-3410, click on *www.dhp.virginia.gov/Pharmacy/leg/Pharmacy%20Law%202007-8-23-07.doc#_Toc171834203*.

Beware of Dispensing Internet Prescriptions

The Board is aware that pharmacists frequently receive solicitations from facilities claiming to be Internet pharmacies or some sort of fulfillment agency. The solicitations usually request that the pharmacy participate in a dispensing scheme that promises enticing fees for each prescription filled. Most of the promised prescriptions are faxed or sent electronically to the participating pharmacy and result from an online questionnaire allegedly reviewed by a physician who then authorizes the prescription. They will even sometimes claim that the patient was examined by a physician via a webcam. However, the use of an online questionnaire or webcam alone as an examination method does not constitute a bona fide practitioner-patient relationship. Therefore, a prescription resulting from these examination methods is not valid and the pharmacist should decline to fill the prescription.

Additionally, pharmacists are occasionally presented prescriptions by patients who reside in Virginia, however, the prescriber's address is in a different location such as Georgia or Puerto Rico. While some of these prescriptions may be legitimate for patients who have just relocated, receiving a prescription from an out-of-state prescriber should prompt the pharmacist to confirm the validity, especially if written for a drug in Schedules II through V. Confirmation of the validity may be achieved by asking the patients questions to determine when and if they were ever physically examined by the physician, and whether the examination took place in the prescriber's office or over the Internet. Ultimately, the pharmacist is obligated to only dispense valid prescriptions, and the pharmacist may need to exercise professional judgment in determining whether a prescription is valid and thus, may be legally dispensed.

A valid prescription, as explained in §54.1-3303, is one that results from a bona fide practitioner-patient relationship. One of the requirements of a bona fide practitioner-patient relationship is that the prescriber must perform or have performed an

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NABP Launches Pharmacy Curriculum Outcomes Assessment Program

NABP launches its Pharmacy Curriculum Outcomes Assessment™ (PCOA®) mechanism in April 2008 for use by schools and colleges of pharmacy in evaluating their curricula. NABP invited schools and colleges of pharmacy to participate in the 2008 administration of the PCOA, scheduled for April 7-18. There will be no fee for participation in this first year of administration.

Those schools and colleges of pharmacy that participate in the April 2008 administration will receive detailed score reports for their students that sit for the assessment, as well as national comparative data. NABP developed the PCOA at the request of schools and colleges of pharmacy and accreditation stakeholders that have expressed a need for a national assessment that is psychometrically validated to assist with measuring curriculum development and student performance.

Details are posted under Assessment Programs on the NABP Web site, *www.nabp.net,* or by contacting NABP Customer Service at custserv@nabp.net.

An e-Educated Consumer is Your Best Customer (Patient)

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

According to the Pew Internet and American Life Project, Online Health Search 2006, 80% of American Internet users, or some 113 million adults, have searched for information on at least one of 17 health topics. Many Americans turn to the Internet before, or instead of, seeking information from their doctor or pharmacist. People want to make better decisions in their lives and therefore seek more in-depth research, research that is offered online.

Patients and caregivers have a vested interest to keep up-to-date on their own or their loved ones' medical conditions. The average doctor's appointment is just 10 minutes – hardly enough time to get into lengthy conversations about treatment options and medication side effects. Long lines, busy and distracted pharmacists, and lack of privacy and confidentiality deter patients from seeking more information from their community pharmacists. It is no wonder then, when patients do not understand medical terminology or want to explore the medication treatment options that are available, they do not call their doctor or pharmacist – they just log on. In the privacy of their home they can find practical information such as lists of foods they should or should not take with certain medical conditions or certain medications. Instead of bothering busy pharmacists who do not appear to have the time to answer questions, they can get peace of mind when dealing with chronic conditions. They surf the net for reassurance and answers to their questions.

But what about the quality of those online sources? Some are better than others; obviously, Medline offered by the National Institutes of Health is a reliable source, but what if the site is sponsored by a pharmaceutical company? How does the consumer know which information to trust? Research suggests that most health information seekers do not check the source and date of the information they find online. Most Internet users use a search engine and key words from their own limited medical knowledge and rely on the algorithms of the search engines to find them reliable Web sites and scientific articles.

How can you, the pharmacist, help your patients find a credible health care information site? Patients need an easy-to-use, comprehensive medical Web site where they can learn about health conditions and medications. Patients should look for Web sites that offer unbiased health information written by medical professionals.

Tell patients to always check sources and dates of the information provided. For example, information on hormone replacement therapy has changed significantly in the last few years. Articles offering advice and recommendations on drug therapy from 10 years ago could be detrimental to the reader.

The patient-doctor-pharmacist triad has changed. We now live in an era of the square – the patient, doctor, pharmacist, and Internet. Help patients understand what they are reading. Go to the sites yourself and confirm the information is reliable and timely. And of course, find time to answer their questions. Look for a soon to be released consumer Web site being developed by ISMP.

FDA Warns against Using OTC Cold Medicines in Babies

FDA issued a public health advisory on January 17, 2008, recommending that over-the-counter (OTC) cough and cold medicines should not be used to treat infants and children younger than 2 years of age, citing the risk of "serious and potentially life-threatening side effects." FDA held a public advisory committee meeting October 18-19, 2007, to discuss the issue, after which many pharmaceutical manufacturers voluntarily withdrew cough and cold medicines marketed for use in this age group.

FDA says the agency is in the process of evaluating the safety of OTC cough and cold medicines in children 2-11 years of age and will announce its recommendations "in the near future."

The public health advisory is available on the FDA Web site at *www.fda.gov/cder/drug/advisory/cough_cold_2008.htm.*

Bayer Diabetes Care Recalls Contour Test Strips

Bayer Diabetes Care recently recalled test strips (sensors) for use with the Contour TS Blood Glucose Meter. The company recalled the product because test strips from specific lots could result in blood glucose readings with a positive bias that could demonstrate 5% to 17% higher test results.

This issue is unrelated to the Contour TS meter itself and pertains only to certain test strips used with the meter. Strips used with other Bayer meters are unaffected.

Health care professionals are advised to check the lot number of the Contour test strips in their inventory and contact Bayer Diabetes Care for information on the return and replacement of strips.

More information is available in the manufacturer's press release at *www.fda.gov/medwatch/safety/2007/contourTS_recall.htm.*

Compliance News

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FDA Takes Action against Compounded BHRT Drugs

FDA sent letters warning seven pharmacy operations that the claims they make about the safety and effectiveness of their so-called bio-identical hormone replacement therapy, or BHRT, products are unsupported by medical evidence, and are considered false and misleading by the agency. FDA has expressed concern that unfounded claims like these mislead women and health care professionals.

The pharmacy operations receiving warning letters use the terms "bio-identical hormone replacement therapy" and "BHRT" to imply that their drugs are natural or identical to the hormones made by the body. FDA regards this use of "bio-identical" as a marketing term implying a benefit for the drug, for which there is no medical or scientific basis.

The FDA news release is available at *www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html.*

Manufacturers to Restrict Distribution of Methadone

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will discontinue supplying this formulation to any facility not meeting these criteria.

The 5 mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the treatment of opioid addiction; it is not FDA-approved for use in the management of pain. This measure comes in response to the reported increase in methadone-related adverse events.

For more information, see "Studies Show Increased Methadone-Associated Mortality Related to Pain Management" in the January issue of the *NABP Newsletter,* available on the NABP Web site at *www.nabp.net.*

New Compounding Standards Effective June 1; USP Offers Webinars

New standards for sterile compounding will become effective on June 1, 2008. United States Pharmacopeia (USP) published the revised General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations" on its Web site in December 2007 to give the compounding community time to implement changes before the effective date.

These revisions tighten standards and conditions for sterile compounding over the previous version of Chapter 797 to help improve patient safety. (See "Sterile Compounding 'Checklist' Revised to Better Protect Patient Health" in the February 2008 issue of the *NABP Newsletter.)* The revisions are included in USP 32–NF 27 and in the second edition of the *Pharmacists' Pharmacopeia,* published in March 2008.

USP is offering a series of educational Webinars and workshops to help compounding professionals appropriately interpret and implement the newly revised standard. The Webinars will provide direct dialogue with two compounding experts and ample time to address questions related to the standard. The workshops will provide added interaction plus hands-on demonstrations related to environmental monitoring, contamination control, and aseptic testing.

Full details on these programs are available on the USP Web site at *www.usp.org/hottopics/generalChapter797.html?hlc.*

CMS Names MSAs, Products for Round Two of DMEPOS Bidding

Centers for Medicare and Medicaid Services (CMS) recently announced the metropolitan statistical areas (MSAs) and product categories for the second round of the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program.

All suppliers must meet quality standards and be accredited by a CMS-recognized accreditation organization, such as NABP, to obtain a contract under the Medicare DMEPOS competitive bidding program. The final deadline for all suppliers to obtain accreditation is September 30, 2009. However, CMS encourages suppliers to seek accreditation as soon as possible to avoid any potential difficulties that would affect their ability to bid.

The competitive bidding program is designed to improve the effectiveness of Medicare's DMEPOS payments, reduce beneficiary out-of-pocket costs, and save the Medicare program money while ensuring beneficiary access to quality DMEPOS items and services. More information, including the lists of MSAs and product categories, is available on the CMS Web site at *www.cms.hhs.gov/CompetitiveAcqforDMEPOS.*

Adverse Event Reporting Requirements in Effect for OTC Products

FDA recently issued new adverse event reporting requirements for manufacturers, packers, and distributors of dietary supplements and over-the-counter (OTC) drug products marketed without an approved application. The new reporting requirements, as described in Public Law 109-462, became effective on December 22, 2007.

The act, as well as the FDA *Guidance for Industry: Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed without an Approved Application,* is available via the FDA MedWatch site at *www.fda.gov/medwatch/otc.htm.*

FDA Rule Calls for Toll-Free Number for Adverse Events on Drug Labels

FDA recently issued an interim final rule requiring certain medication labels to include a toll-free number for reporting adverse events. The interim final rule codifies provisions of the proposed rule "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products" that became effective on January 1, 2008, under the FDA Amendments Act of 2007. The rule does not apply to over-the-counter medications approved as new drugs if the product packaging includes a manufacturer's or distributor's toll-free number for reporting complaints.

To allow manufacturers, dispensers, and pharmacies time to update their labeling and systems to comply with the new requirements, FDA will delay enforcement actions regarding these regulations until January 1, 2009.

More information is available in the *Federal Register* (Docket No. 2003N-0342) at *www.fda.gov/OHRMS/DOCKETS/98fr/E7-25426.pdf.*

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appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically. Additionally, except for medical emergencies, the examination of the patient shall have been performed by the practitioner, within the group in which he or she practices, or by a consulting practitioner prior to issuing a prescription.

For more information on the issuance of a prescription pursuant to a bona fide practitioner-patient relationship, please refer to §54.1-3303 at *www.dhp.virginia.gov/Pharmacy/leg/Pharmacy%20Law%202007-8-23-07.doc#_Toc171834162*. To review the requirements when declining a prescription, refer to Regulation 18VAC110-20-270 at *www.dhp.virginia.gov/Pharmacy/leg/Pharmacy_11292006.doc#_Toc153072932*.

Best Practices for Reducing Medication Errors

An ad hoc committee of the Board began specific discussions in March regarding the need to increase patient safety by reducing medication errors. The committee is currently reviewing other states' requirements for pharmacies to have some type of ongoing quality improvement program. These quality improvement programs are generally designed to analyze medication errors and promote changes within the specific pharmacy's workflow to decrease the possibility of recurring medication errors. Additionally, the committee discussed the requiring of continuing education (CE) specifically related to patient safety and Virginia law. Another source of discussion involved the Board publicizing best practices or standards that have been shown to reduce the occurrence of medication errors.

Patient safety issues have always been an important topic to the Board and related discussions will continue to evolve. It is important for pharmacists and pharmacy technicians to acknowledge that medication errors will occur. However, it is possible to reduce the number of medication errors and to offer better patient care through analyzing the causes of those errors and making process changes to reduce the opportunity for medication errors to recur.

Free Continuing Education

The Virginia Department of Health Professions has partnered with the Virginia Commonwealth University (VCU) School of Medicine in the development of an online pain management curriculum called VCU Chronic Nonmalignant Pain Management. This curriculum emphasizes current issues in the management of pain through a case-based format and offers ongoing access to practice resources in pain management. The Board of Pharmacy has approved this course for CE. Upon completion of the program, pharmacists and pharmacy technicians will be granted three hours of CE. Please note that it does not need to be completed in one sitting and may be used as a reference tool even after completing the program. Additionally, please be aware that as a Virginia Board-approved CE course this program may not qualify as CE for other states or for other certifications.

Registration is free and requires the entry of a Virginia license number and the following case-sensitive access code: "Virginia Pain." Registration for the course may be accessed at *https://www.apps.som.vcu.edu/vculms/registration/calendar.aspx*. Questions and comments can be directed to Leanne M. Yanni, MD, creator and editor, at lyanni@mcvh-vcu.edu.

Reminders

Generic Substitution

When a prescriber wishes to prohibit substitution with a therapeutically equivalent drug, the prescriber must record on the prescription "brand medically necessary." This phrase, however, is not required to be recorded in the prescriber's own hand writing, unless the prescription is for a patient eligible for Medicaid reimbursement. For any other patient, the phrase may be recorded in any manner the prescriber wishes, as long as it is clearly indicated. Therefore, the phrase may be checked, circled, stamped, typed, etc. For an oral prescription, the prescriber or prescriber's agent must simply inform the pharmacist that the branded drug is medically necessary, then the pharmacist must record the phrase "brand medically necessary" onto the oral prescription.

For more information on substituting with therapeutically equivalent drug products, click on *www.dhp.virginia.gov/Pharmacy/pharmacy_faq.htm#PresBlank*.

Electronically Transmitted Prescriptions

The electronic transmission of prescriptions is allowed under Board regulation 18VAC110-20-285; however, the regulation states that it must comply with other requirements of federal law. Currently, DEA has not recognized via federal law or regulation the electronic transmission of Schedules II through V. Therefore, only Schedule VI drugs may be electronically transmitted.

When prescriptions are electronically transmitted, the prescription travels electronically from the prescriber's computer to either the pharmacy's computer or to the pharmacy's fax machine. Right now, it can be difficult for a pharmacist to discern whether the recently received prescription on the fax machine came via traditional faxing methods (hard copy placed on prescriber's fax machine and sent to pharmacy's fax machine) or whether it was truly electronically transmitted. Many prescription transmitting programs will record language on the prescription indicating that it was electronically transmitted; however, pharmacists may need to contact the prescriber's office to inquire as to how the prescription was transmitted if they are uncertain. It is important to determine the method of transmission, since the rules for faxing prescriptions and for electronically transmitting prescriptions are different.

Unlike electronically transmitted prescriptions, prescriptions for drugs in Schedules III through VI may be faxed to the pharmacy, along with Schedule II in limited situations. These faxed prescriptions must bear the prescriber's manual signature, because an electronic signature is not acceptable for a faxed prescription. With respect to rules for electronically transmitted prescriptions, only prescriptions for Schedule VI drugs may be electronically transmitted.

DEA has stated that a pharmacist who receives an electronically transmitted prescription for a Schedule III through V drug may treat the prescription as an oral prescription by contacting the prescriber's office to verify the information and record the prescriber agent's name, if applicable.

Additionally, please note that if the prescriber prepares the prescription electronically and prints it out to give to the patient, then the prescription must bear a manual signature.

For more information on the various methods of transmitting prescriptions, click on guidance document 110-35 at *www.dhp.virginia.gov/Pharmacy/guidelines/110-35%20Requirements%20for%20prescriptions.doc*.

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